(b) If we are not charging you for the first two hours of search time, under paragraph (c) of § 402.155, and those two hours are spent on a computer search, then the two free hours are the first two hours of the time needed to access the information in the computer.

(c) If we are not charging you for the first 100 pages of duplication, under paragraph (b) or (c) of § 402.155, then those 100 pages are the first 100 pages of photocopies of standard size pages, or the first 100 pages of computer printout.

* * * * *

[FR Doc. 98–17104 Filed 6–26–98; 8:45 am]
BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 54

[Docket No. 93N–0445]

Financial Disclosure by Clinical Investigators; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of February 2, 1998 (63 FR 5233). The document issued regulations requiring the sponsor of any drug, including a biological product, or device marketing application (applicant), to submit certain information covering the compensation to, and financial interests of, any clinical investigator conducting certain clinical studies. The document was published with an error. This document corrects that error.

EFFECTIVE DATE: February 2, 1999.

FOR FURTHER INFORMATION CONTACT: Mary C. Gross, Office of External Affairs, Food and Drug Administration (HF–60), 5600 Fishers Lane, Rockville, MD 20857, 301–827–3440, FAX 301–594–0113.

SUPPLEMENTARY INFORMATION: In FR Doc. 98–2407 appearing on page 5233 in the **Federal Register** of February 2, 1998, the following correction is made:

§ 54.4 [Corrected]

On page 5251, in the first column, in § 54.4 *Certification and disclosure requirements*, paragraph (a), line 3, ''519(k)'' is corrected to read ''510(k)''.

Dated: June 19, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–17145 Filed 6–26–98; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 97F–0440]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 1,6-hexanediamine, *N, N′*-bis(2,2,6,6-tetramethyl-4-piperidinyl)-, polymers with morpholine-2,4,6-trichloro-1,3,5-triazine reaction products, methylated, as a stabilizer for olefin polymers intended for use in contact with food. This action is in response to a petition filed by Cytec Industries, Inc.

DATES: The regulation is effective June 29, 1998; written objections and requests for a hearing by July 29, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of November 6, 1997 (62 FR 60095), FDA announced that a food additive petition (FAP 8B4562) had been filed by Cytec Industries, Inc., c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of 1,6-hexanediamine, *N, N′*-bis(2,2,6,6-tetramethyl-4-piperidinyl)-, polymers with morpholine-2,4,6-trichloro-1,3,5-triazine reaction products, methylated, as a stabilizer for olefin polymers complying with 21 CFR 177.1520 intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe and the additive will achieve its intended technical effect. Therefore, the regulations in § 178.2010 should be amended as set forth below.

FDA's review of this petition indicates that the additive may contain trace amounts of formaldehyde as an impurity. The potential carcinogenicity of formaldehyde was reviewed by the Cancer Assessment Committee (the Committee) of FDA's Center for Food Safety and Applied Nutrition. The Committee noted that for many years, formaldehyde has been known to be a carcinogen by the inhalation route, but the Committee concluded that these inhalation studies are not appropriate for assessing the potential carcinogenicity of formaldehyde in food. The Committee's conclusion was based on the fact that the route of administration (inhalation) is not relevant to the safety of formaldehyde residues in food and the fact that tumors were observed only locally at the portal of entry (nasal turbinates). In addition, the agency has received literature reports of two drinking water studies on formaldehyde: (1) A preliminary report of a carcinogenicity study purported to be positive by Soffritti et al. (1989), conducted in Bologna, Italy (Ref. 1); and (2) a negative study by Til et al. (1989), conducted in The Netherlands (Ref. 2). The Committee reviewed both studies and concluded, concerning the Soffritti study, '' * * * that data reported were unreliable and could not be used in the assessment of the oral carcinogenicity of formaldehyde'' (Ref. 3). This conclusion is based on a lack of critical detail in the study, questionable histopathological conclusions, and the use of unusual nomenclature to describe the tumors. Based on the Committee's evaluation, the agency has determined that there is no basis to conclude that formaldehyde is a carcinogen when ingested.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for